



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/810,829

03/29/2004

Alan D. King

04-100

9996

7590

03/30/2007

Marvin S. Townsend
Patent Attorney
8 Grovepoint Court
Rockville, MD 20854

EXAMINER

FERNANDEZ, SUSAN EMILY

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

03/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/810,829

Applicant(s)

KING ET AL.

Examiner

Susan E. Fernandez

Art Unit

1651

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 February 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☒ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 25, 26, 28, 29, 31, 38, 40, 44, 47, 49, 50, 52 and 53.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.

Leon B. Lankford, Jr.
Primary Examiner
Art Unit 1651

ATTACHMENT TO ADVISORY ACTION

The response filed February 22, 2007, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

The amendment filed February 22, 2007, has not been entered since the new language in the proposed amendment requires consultation of the specification to confirm support for the new language, particularly the proposed amendment in the specification and the claims that the needle electrode is “non-hollow” and that the coating is on the outside. Furthermore, the amendment would require a new search since the claims previously did not require a “non-hollow” needle electrode or a coating on the outside of the electrode. Therefore, denial of entry of the proposed amendment is proper at this after-final stage of prosecution.

The majority of applicant’s argument assumes entry of the non-entered amendment, and is thus directed to subject matter which is not presently entered into the claims. However, to the extent the applicant’s argument is applicable to the claims as pending, it does not demonstrate error for the reasons of record. With respect to the Weidlich reference, the applicant has not provided support for the assertion that “...the polymers remain in the interstitial portions of the tissues, outside the biological cells.” Moreover, the polymer of the Weidlich electrode is indeed released from the electrode since Weidlich et al. indicates that “as a result of modifying the electrode structure, the depository effect of the polymer/steroid coating is increased” (column 3, lines 37-39). Clearly, the Weidlich electrode meets the structural limitations (releasable coating) recited in the instant claims, and therefore meet the recited intended use limitations (delivery into

Art Unit: 1651

cells). Additionally, applicant indicates that claim 1 of Weidlich et al. demonstrates that the reference teaches that the non-macromolecular steroid is not delivered into the cells by the applied electric field. However, the recitation of diffusion in claim 1 of Weidlich et al. does not mean that diffusion is not induced by the applied electric field. Further still, the applicant also presents the Declaration of Alan King under Rule 132 as support for their arguments; however, at this stage of prosecution, the declaration has not been entered.

Regarding the Hofmann reference, it is respectfully noted that Weidlich et al. is combined with Hofmann in order to provide motivation for using needle-shaped electrodes set up in electrode arrays. No other structural features of Hofmann are suggested for the modification of the Weidlich invention.

With respect to the Zewert, Widera, and Lerner references, these references are combined with Weidlich et al. to provide motivation for the delivery of polynucleotides, DNA vaccines, or protein-based vaccines by the effects of an applied electric field. There is no suggestion to use the equipment of Zewert, Widera, and Lerner. It is in the combination of these references with the Weidlich and Hofmann references that a needle electrode with an outside, static coating of polynucleotides, DNA vaccines, or protein-based vaccines releasable by an applied electric field, is rendered obvious.

In sum, the rejections of record must be maintained.

No claims are allowed.

Art Unit: 1651

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan E. Fernandez
Assistant Examiner
Art Unit 1651

Leon B. Lankford, Jr.
Primary Examiner
Art Unit 1651

sef